Supreme Court, U.S.
FILED
JUL 18 2002
OFFICE OF THE CLERK

No. 01-1835

IN THE

Supreme Court of the United States

JOSEPH BRANDEIS STAHL,

Petitioner,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF IN OPPOSITION

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STATEMENT PURSUANT TO RULE 29.6

Respondent, Novartis Pharmaceuticals Corporation, is an indirect, wholly-owned subsidiary of Novartis AG. Novartis Pharmaceuticals Corporation's parent companies are:

(1) Novartis Finance Corporation;

(2) Novartis Corporation;

(3) Novartis Holding AG, a Swiss company; and

(4) Novartis AG, a Swiss company, publicly traded on the New York Stock Exchange (symbol: NVS).

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STATEMENT OF THE CASE

On April 5, 1999, Petitioner filed suit against Novartis Pharmaceuticals Corporation ("Novartis"), the manufacturer of the prescription drug Lamisil Tablets® ("Lamisil®"). Petitioner alleged that Lamisil® damaged his liver by causing symptomatic hepatobiliary dysfunction, including cholestatic hepatitis. As Petitioner admitted and as the courts below determined, however, the labeling for Lamisil® at the time Petitioner was prescribed Lamisil® contained warnings concerning the complications allegedly suffered by Petitioner.[1]

The district court granted summary judgment in favor of Novartis after finding the Lamisil® label adequate as a matter of law pursuant to Louisiana's "learned intermediary doctrine." Under this doctrine, a prescription drug manufacturer does not have the obligation to directly warn patients who use a drug of its potential risks. Rather, the manufacturer has a duty to inform the prescribing physician — the learned intermediary — of the potential side effects and risks that arise from the drug's use. *Zachary v. Dow Corning Corp.*, 884 F. Supp. 1061, 1065 (M.D. La. 1995); *Mikell v. Hoffman-LaRoche, Inc.*, 649 So. 2d 75, 79 (La. App. 1 Cir. 1994), citing *Cobb v. Syntex Lab.*, 444 So. 2d 203, 205 (La. App. 1 Cir. 1983).

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1. As reproduced in the Fifth Circuit's opinion below, the labeling for Lamisil® contained the following language:

> WARNINGS
>
> Rare cases of *symptomatic hepatobiliary dysfunction including cholestatic hepatitis* have been reported. Treatment with Lamisil (terbinafine hydrochloride tablets) *Tablets should be discontinued if hepatobiliary dysfunction develops (see PRECAUTIONS).*

See Pet. App. at A15 and A34.

Petitioner appealed the district court's ruling to the Fifth Circuit. On *de novo* review, the Fifth Circuit affirmed the district court's ruling, finding that there was no material issue of disputed fact, and that the Lamisil® label was adequate as a matter of law. *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254 (5th Cir. 2002).

REASONS FOR DENYING THE WRIT

The decisions of the courts below reflect a straightforward application of Louisiana law to the undisputed facts of this case. Notwithstanding Petitioner's contention that a footnote in the Fifth Circuit's opinion regarding the admissibility of subsequent changes to the Lamisil® label conflicts with the Eighth Circuit's treatment of a similar issue more than a decade ago in *O'Dell v. Hercules, Inc.*, 904 F.2d 1194 (8th Cir. 1990), the Fifth Circuit's decision in fact creates no circuit conflict, and Petitioner's request for writ of certiorari should be denied.

I. Misstatements of Fact

The Petition contains numerous misstatements, most of which are not relevant to Petitioner's arguments. Pursuant to the requirements of Supreme Court Rule 15.2, however, Novartis identifies particular misstatements in the Petition that could conceivably "bear on what issues properly would be before the Court if certiorari were granted." Sup. Ct. Rule 15.2.

- Petitioner's bare contention that subsequent changes to the Lamisil® label were "involuntary" (Pet. at 9) is unsupported by the record (and wrong).

- Petitioner's allegations regarding Lamisil® advertising (Pet. at 4) are unsupported by the record (and incorrect).

- The medical records and testimony of Petitioner's treating physicians do not support Petitioner's allegation that he was "almost killed" as a result of his injuries (Pet. at 4).

- The evidence in the record does not support Petitioner's incorrect allegation that the Lamisil® label, warnings, and literature from Novartis established a medical monitoring regimen that mandated a "delay in commencement" of liver–function tests "until the 7th week" of taking Lamisil® (Pet. at 4, 8, 20). Similarly, Petitioner cannot point to any evidence in the record to support his allegation that patients taking Lamisil® should undergo "pre-treatment, and earlier than 7th-week liver–function testing" (Pet. at 8).

- There is no evidence to support Petitioner's wrong and inflammatory statements that 17 people have been "killed" by Lamisil® (Pet. at 4, 8, 20), or that Novartis "lied," "concealed" information, and "downplayed" levels of risk associated with Lamisil® (Pet. at 5-6).

- The record contains no support for Petitioner's incorrect statement that Lamisil® is "inherently hepatotoxic" (Pet. at 8).

- Petitioner misstates the report of Dr. George (Pet. at 8). The record reflects that Dr. George never rendered an opinion that the labeling for Lamisil® was inadequate, nor did he propose a mandatory testing regimen for the millions of individuals who are prescribed Lamisil®.

- Petitioner misstates the testimony of Dr. Regenstein (Pet. at 20-21). The record reflects that Dr. Regenstein, the Petitioner's treating heptologist and not the learned intermediary in this case, had knowledge of the risk of hepatobiliary dysfunction and its unpredictable nature. Furthermore, Dr. Regenstein claimed no expertise in drug product warnings.

- Petitioner misstates the Lamisil® label by alleging that the term "mild" in the label was used to describe adverse events generally (Pet. at 9).

- There is no legal support for Petitioner's claim that it is "axiomatic" and "uniformly held" that a subsequent change in a prescription label establishes that a "pre-change warning was inadequate" (Pet. at 9). Even the 35-year old California state court opinion that Petitioner cites for this proposition does not support his argument. *See Love v. Wolfe*, 249 Cal. App. 2d 822, 831 (Cal. App. 3d Dist. 1967) (holding only that there was no prejudicial error created by admitting subsequent label because subsequent label could have been admitted for purpose of impeaching specific testimony of defendant's witnesses, and because defendant failed to seek limiting instruction at time evidence was introduced).

- Petitioner misidentifies Respondent as a Swiss Corporation. Novartis Pharmaceuticals Corporation is a Delaware Corporation with its principal place of business in the State of New Jersey.

II. The Decisions Below Reflect An Application of Settled Law to Undisputed Facts.

The decisions of the district court and Fifth Circuit in this case reflect an uncontroversial application of Louisiana law to undisputed facts. State and federal courts uniformly have held that a warning is adequate as a matter of Louisiana law if it informs the doctor of the potential adverse reactions that are the basis of the lawsuit. *Anderson v. McNeilab, Inc.*, 831 F.2d 92, 93 (5th Cir. 1987); *Bealer v. Hoffman-La Roche*, 729 F. Supp. 43, 44-45 (E.D. La. 1990); *Calhoun v. Hoffman-La Roche, Inc.*, 2000 WL 202067, at *5 (La. App. 1 Cir. 2000); *Kinney v. Hutchinson*, 468 So. 2d 714, 718 (La. App. 5 Cir. 1985); *Cobb v. Syntex Lab.*, 444 So. 2d 203, 206 (La. App. 1 Cir. 1983). The courts below applied this rule of law to the undisputed facts in the record concerning: (1) the content of the Lamisil® product information; (2) the Petitioner's alleged injury; and (3) the treating physician's knowledge of the risks that are at issue.

None of Petitioner's arguments — either below or in his Petition for Writ of Certiorari — creates or identifies a disputed fact that is material to this analysis under the learned intermediary doctrine. The Fifth Circuit correctly determined that the Lamisil® product information was adequate as a matter of law and affirmed entry of summary judgment in favor of Novartis.[2] Moreover, as the opinions of the district

2. Previous decisions by federal and state courts applying Louisiana law demonstrate the straightforward nature of the analysis in this case. *See, e.g., Wheat v. Pfizer, Inc.*, 31 F.3d 340 (5th Cir. 1994) (affirming summary judgment); *Anderson*, 831 F.2d 92 (same); *Zachary v. Dow Corning Corp.*, 884 F. Supp. 1061, 1065 (M.D. La. 1995) (granting summary judgment); *Bealer*, 729 F. Supp. 43 (same); *Calhoun*, 2000 WL 202067 (affirming summary judgment); *Mikell*, 649 So. 2d at 75 (same); *Kinney*, 468 So. 2d 714 (same); *Cobb*, 444 So. 2d 203 (same).

court and the Fifth Circuit illustrate, the courts below took great pains to address all of the arguments raised by Petitioner.

III. No Circuit Conflict Exists Concerning the Application of Federal Rule of Evidence 407 to Subsequent Prescription Drug Warnings.

There is no conflict between the Fifth Circuit's holding in this case and the Eighth Circuit's decision in *O'Dell v. Hercules, Inc.*, 904 F.2d 1194 (8th Cir. 1990). In footnote 10 of its opinion in this case, the Fifth Circuit noted in *dicta* that changes made to the Lamisil® label subsequent to the Petitioner's injury could not be considered because they constituted a subsequent remedial measure under Fed. R. Evid. 407. This application of Rule 407 is in complete accord with the Eighth Circuit's application of Rule 407 in a similar case involving prescription drugs.

In *DeLuryea v. Winthrop Lab.*, the Eighth Circuit examined the application of Rule 407 in the specific context of subsequent remedial changes in prescription drug labeling. 697 F.2d 222, 229 (8th Cir. 1983). The court concluded that Rule 407 "requires exclusion of evidence of subsequent remedial changes in [a drug manufacturer's] warning literature." *Id.* (relying on *Werner v. Upjohn Co.*, 628 F.2d 848, 859-60 (4th Cir. 1980), *cert. denied*, 449 U.S. 1080 (1981), in which the Fourth Circuit found the application of Rule 407 particularly appropriate in the context of subsequent remedial changes in prescription drug labeling because it encourages "early, unilateral action by the drug companies to improve their warnings" and supports applicable FDA labeling regulations).

Petitioner does not cite — much less address — the Eighth Circuit's opinion in *DeLuryea*. Rather, he cites to *O'Dell*, an Eighth Circuit opinion that does not involve prescription drugs, and which in any case is not inconsistent with the *dicta* in footnote 10 of the Fifth Circuit's opinion in this case. *O'Dell v. Hercules, Inc.*, 904 F.2d 1194 (8th Cir. 1990) (addressing Rule 407 issues in context of chemical exposure case).

IV. The "Voluntariness" Issue Petitioner Asks This Court To Review Was Not Raised By Petitioner Or Considered By The Courts Below.

Petitioner also relies on the Eight Circuit's opinion in *O'Dell* to support a new argument not made below that "involuntary" remedial measures are not subject to Rule 407. This argument is irrelevant to this case, however, because there was no record evidence or argument of any kind in the courts below that would indicate that subsequent changes to the Lamisil® label were "involuntary." Further, as the Fourth Circuit explained in *Werner*, the unique relationship between FDA and manufacturers of prescription drugs makes any "voluntariness" analysis under Rule 407 inappropriate in prescription drug cases. 628 F.2d at 859-60.

Moreover, because Petitioner did not raise his "voluntariness" argument concerning Fed. R. Evid. 407 in the district court or the Fifth Circuit, neither court addressed this issue. As a general rule, a question presented in the petition for writ of certiorari but not raised in the court of appeals is not properly before the Supreme Court. *See Delta Airlines v. August*, 450 U.S. 346, 362 (1981) (issue of the district judge's alleged abuse of discretion in denying defendants' costs was not properly before the Court because

not raised in the Court of Appeals); *see also Campbell v. Louisiana*, 523 U.S. 392, 403, 118 S. Ct. 1419, 1425 (1998) (refusing to address issue raised by petitioner on certiorari where "neither the Louisiana Supreme Court nor the Louisiana Court of Appeal discussed this contention" and petitioner had "made no effort to meet his burden of showing this issue was properly presented to the Louisiana appellate courts"). In any event, the Fifth Circuit obviously could not have created a split in the circuits on this "voluntariness" issue given that the issue was neither raised nor addressed below.

V. Petitioner's Allegations of Evidentiary Error Arising from Rule 407's Impeachment Exclusion Do Not Implicate Any Certworthy Issue.

Petitioner's contention that the courts below erred by not admitting subsequent label changes as evidence of impeachment under Rule 407 raises no certworthy issue. It is axiomatic that this Court does not sit as a court of error correction. There was no error below in any event, because the subsequent Lamisil® labels do not contradict any testimony by Novartis or its witnesses. Thus, as the Fifth Circuit and the district court correctly recognized below, such subsequent labeling changes are not admissible under Rule 407. This conclusion is in complete accord with the law of other federal circuits. *See Probus v. K-Mart, Inc.*, 794 F.2d 1207, 1210 (7th Cir. 1986) ("impeachment" exception under Rule 407 cannot be used to argue that subsequent remedial measure "'impeaches' a defendant's contention that he was exercising due care," because to allow such a broad exception would elevate the exception to the rule).

CONCLUSION

The Fifth Circuit's application of the Louisiana learned intermediary doctrine in this case was correct and uncontroversial. No conflict between the circuits was created. The Petition for Writ of Certiorari should be denied.

Respectfully submitted,

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